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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DIRAMIO, JACQUELINE A

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/584,484	Applicant(s) BRANDER ET AL.	
	Examiner JACQUELINE DIRAMIO	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 17-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/23/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1 – 12 and 17 – 19, in the reply filed on September 22, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claim 13 is acknowledged as withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claims 1-13 and 17-19 are pending. Claims 1-12 and 17-19 are under examination.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

On page 12, line 6, the "array substrate 28" is disclosed with respect to Figure 1, however, this reference number is not displayed in Figure 1.

On page 14, line 27, the "diameter 31" is disclosed with respect to Figure 2, however, this reference number is not displayed within Figure 2.

On page 15, lines 27-34, the "chip 32," "substrate 28," "support layer 6," "nanopores 8," "stamp 33," "PMMA 34," and "substrate 35" are disclosed with respect to Figure 3, however, these reference numbers are not present in Figure 3.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing

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sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to because of the following informalities:

On page 11, a brief description of Figures 1 – 3 is disclosed, however, Figure 4 is missing from this brief description of the drawings.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1 – 5, 8 – 12, 17 and 18 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by Freeman et al. (US 2003/0104512).

Freeman et al. teach a biosensor (assay chip) for investigation of a functionality of non-lipid molecules and their interactions with molecules, comprising:

- a) a porous (nanopore) substrate 80 having a plurality of pores (nanopores);
- b) a substantially planar membrane 82 (support layer) deposited on said porous substrate and having a plurality of nanopores corresponding to said pores of said porous substrate;
- c) a cellular layer 84 (biologically effective layer) configured to host at least one of a non-lipid molecule and functional molecule, deposited on said membrane and covering the plurality of nanopores, resulting in accessible nanopores from both sides of the cellular layer for measurements (see Figures 2, 3, 6 and 7; and paragraphs [0015], [0029], [0033], [0034], [0039]-[0042], [0045], [0050], and [0052]).

With respect to Applicant's claim 2, a surface of the membrane can be chemically modified with a hydrophobic polymer coating resulting in a support promotion layer (see Figure 3; and paragraph [0042]).

With respect to Applicant's claim 3, the membrane (support layer) can comprise silicon nitride or silicon oxide, and the substrate can comprise silicone (see paragraphs [0029] and [0053]).

With respect to Applicant's claims 4, 5, 17 and 18, the thickness of the substrate is preferably around 525 microns thick, with nanopores ranging from 100 nm to 10 microns, which results in an aspect ratio in the range of 0.05 to 50 (see paragraphs [0041] and [0052]).

With respect to Applicant's claim 8, the cellular layer can be a biomembrane isolated from eukaryotic cells, wherein a lipid bilayer can be formed as a functional layer of supramolecular assembly (see paragraphs [0033], [0034], [0036], and [0042]).

With respect to Applicant's claim 9, the non-lipid molecules can be from a natural source selected from eukaryotes or prokaryotes (see paragraphs [0033], [0034] and [0036]).

With respect to Applicant's claim 10, the cellular layer can host a non-lipid molecule, such as a synthetic compound (see paragraphs [0039] and [0040]).

With respect to Applicant's claim 11, the biomembranes and lipid bilayer can comprise a non-lipid or functional molecule, whereby the functional molecule is produced via recombinant DNA or RNA technologies (see paragraph [0034]).

With respect to Applicant's claim 12, the cellular layer is made from at least one intact living cell (see paragraphs [0033], [0034], [0036], [0039], and [0042]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 6, 7 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al. (US 2003/0104512), as applied to claim 1 above, and further in view of Beattie (US 5,843,767).

The Freeman et al. reference, which is discussed in the 102 rejection above, fails to teach that the nanopores are arranged as sections with a particular area, with a particular distance between each other.

Beattie teaches a microfabricated, flowthrough porous apparatus for detecting binding reactions, wherein the apparatus comprises a porous silicon wafer (substrate) with integral sample wells. The pores or nanochannels of the silicon wafer are developed within regions on the wafer with specific nanochannel diameters, densities of the regions, and center-to-center spacing between the nanochannels. By determining optimal diameters, density, and center-to-center spacing, a high density array of nanochannels is created on the wafer, which further yields a high surface area to volume ratio to tether various biomolecules to the nanoporous supports or wafers (see Figures 1A, 1B, and 3; Abstract; column 5, lines 28-67; and column 6, lines 1-14; and Examples 1-3).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the biosensor of Freeman et al. specific densities of the nanopore regions and center-to-center spacing between the nanopores as taught by Beattie because Beattie teaches the benefit of determining optimal diameters, density, and center-to-center spacing of nanopores or nanochannels provided on a substrate in order to create a high density array of nanochannels on the substrate, which further yields a high surface area to volume ratio to tether various biomolecules to the nanoporous supports or wafers.

Conclusion

7. No claims are allowed.

8. The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Parikh et al. (WO 03/016040) teach a membrane structure for studying various biological events, such as cell-signaling events or the function of integral membrane proteins, wherein the structure comprises a substrate, a nanoporous inorganic oxide support material and a lipid membrane on said nanoporous support material (see Abstract; Figure 1; p2, lines 26-29; p3, lines 1-28; p4, lines 13-16; p6, lines 28-29; and p7, lines 1-21).

Kelemen et al. (US 5,716,526) teach a method for separating liposomes or lipid complexes in a fluidic medium by passing the medium through a composite filter, wherein the filter comprises at least one layer of a porous substrate and a membrane thereon, which comprises a smaller pore size than the substrate layer(s) (see Abstract; Figures 2A-3D; column 1, lines 60-67; column 2, lines 1-39; column 4, lines 5-67; and column 5, lines 1-36).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE DIRAMIO whose telephone number is (571)272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline DiRamio/
Examiner, Art Unit 1641

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

12/4/09